

Atty. Dkt. No. 077319-0225

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Ralph M. ELLISON et al.

Title: COMPOSITIONS AND METHODS FOR THE TREATMENT OF
PRIMARY AND METASTATIC NEOPLASTIC DISEASES USING
ARSENIC COMPOUNDS

Appl. No.: 09/173,531

Filing Date: 10/15/1998

Examiner: J. Pak

Art Unit: 1616

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

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RELEVANCE OF EACH DOCUMENT

Any document listed on the attached PTO/SB/08 was cited as being relevant during the prosecution of the corresponding European applications. A copy of each of the European Search Reports is attached setting forth the portion of each document considered relevant by the examiners. An English-language counterpart of the foreign-language documents has not been provided. The absence of a translation or an English-language counterpart document does not relieve the PTO from its duty to consider any submitted document (37 CFR §1.98 and MPEP§609).

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

FEE

A fee in connection with submission of a supplemental information disclosure statement under 37 CFR §1.97(c) in the amount of \$180.00 in accordance with 37 CFR §1.17(p) is attached.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 11 May 2004

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: May 11, 2004 <i>(use as many sheets as necessary)</i>		Complete if Known <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>09/173,531</td> </tr> <tr> <td>Filing Date</td> <td>10/15/1998</td> </tr> <tr> <td>First Named Inventor</td> <td>Ralph M. ELLISON</td> </tr> <tr> <td>Group Art Unit</td> <td>1616</td> </tr> <tr> <td>Examiner Name</td> <td>J. Pak</td> </tr> <tr> <td>Attorney Docket Number</td> <td>077319-0225</td> </tr> </table>		Application Number	09/173,531	Filing Date	10/15/1998	First Named Inventor	Ralph M. ELLISON	Group Art Unit	1616	Examiner Name	J. Pak	Attorney Docket Number	077319-0225
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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
			FR 2 699 820		Eric PICHOT	12/24/1992		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		International Search Report	
		Matthew BLOCK et al., "Biological Studies with Arsenic IV. The Histopathologic Effect of Arsenic Upon the Hematopoietic Tissues of Patients with Leukemia", The Journal of Laboratory and Clinical Medicine, Vol. 41, No. 4, 4/1953, pp. 499-515.	
		P. ROUSSELOT et al., "Arsenic derivatives: Old drugs for new indications!, Les Derives Arsenicaux: De Vieux Medicaments Pour Des Indications Renouvelees", Hematologie, Vol. 4, no. 3, 5/1998, pp. 95-97.	
		P. ROUSSELOT et al., "Arsenic trioxide (AS2O3) and Melarsoprol induce myeloma cell apoptosis in vitro with a preferential effect on tumoral cells in patients' bone marrow", BLOOD, vol. 90, no. 10, 11/15/1997, page 325A.	
		Z. XIE et al., "Melarsoprol and arsenic trioxide increase cell death on doxorubicin-resistant human leukemia and myeloma cells by regulating expression of BCL-2 apoptosis regulatory family", BLOOD, vol. 90, no. 10, 11/15/1997, pp. 495 A.	
		DATABASE EPODOC 'Online! European Patent Office, the Hague, NL., CN1180563, 5/6/1998, Zhao QINGTUAN: XP002260136 *abstract*.	
		International Search Report	
		Edward B. SILBERSTEIN, "Radionuclide Therapy of Hematologic Disorders", Seminars in Nuclear Medicine, Vol. 9, No. 2, 4/1979, pp. 100-107.	
		David A. SEARS MD, "History of the Treatment of Chronic Myelocytic Leukemia", American Journal of the Medical Sciences, Vol. 296, No. 2, 8/1988, pp. 85-86.	

Examiner Signature	Date Considered
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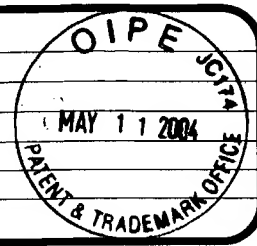
¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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		Zhi-Xiang SHEN et al., "Use of Arsenic Trioxide (As ₂ O ₃) in the Treatment of Acute Promyelocytic Leukemia (APL); II. Clinical Efficacy and Pharmacokinetics in Relapsed Patients", Blood, Vol. 89, No. 9, 5/1997, pp. 3354-3360.	
		International Search Report	
		W. ZHANG et al., "The induction of apoptosis and cell cycle arrest by arsenic trioxide in lymphoid neoplasms", Leukemia (1998), vol. 12, no. 9, 9/1998, pp. 1383-1391.	
		John G. KIDD, "EFFECTS OF ARSENIC AZOPROTEINS ON MOUSE LYMPHOMA CELLS IN VIVO* With Observations on the Effects of Other "Anti-Lymphoma" Agents and On the Susceptibility to these Effects of Lymphoma Cells of Various Types", Journal of Experimental Medicine, vol. 108, 1958, pp. 665-684.	
		Jacques DEBRAY, "Treatment of Hodgkin's Disease", Therapie, vol. 9, 1954, pp. 106-118.	
		G. LOTTI, "Abandonment of arsenic in medical therapy of malignant granuloma (Hodgkin's disease): is it justified?!" Revue Medicale Du Moyen-Orient, vol. 24, no. 2, 3/1967 pp. 110-111.	
		International Search Report	
		S. ROSNER, "Immunological Enhancement of Chemotherapy in Advanced Brain Cancer", ACTA. NEUROL. LATINOAMER. Vol. 21, No. 4, 1975, pp. 126-132.	
		S. SHIMOTSUURA, "STUDIES ON THE ANTINEOPLASMIC ACTIONS OF AS ₂ O ₃ " Shika Gakuho - Journal of Tokyo Dental College Society, vol. 86, no. 8, 1986, pp. 1237-1253.	
		P. ZHANG et al., "Treatment of Acute Promyelocytic Leukemia with Intravenous Arsenic Trioxide" Zhonghua Xueyexue Zazhi - Chinese Journal of Hematology, vol. 17, no. 2, 2/1996, pp. 58-60.	
		D.A. Sears, "History of the Treatment of Chronic Myelocytic Leukemia", American Journal of Medical Sciences, vol. 296, no. 2, 8/1988, pp. 85-86.	
		Y.L. KWONG et al., "Delicious Poison: Arsenic Trioxide for the Treatment of Leukemia", Blood, vol. 89, no. 9, 5/1997, pp. 3487-3488	
		Edward B. SILBERSTEIN, "Radio nuclide Therapy of Hematologic Disorders", Seminars in Nuclear Medicine, vol. 9, no. 2, 4/1979, pp. 100-107.	

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